

Shaughnessy No.: 105501

Date Out of EAB: 5/10/88

FROM: Patrick W. Holden, Team Leader *C.E. for*
Ground-Water Team
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

TO: R. Taylor/Erumsele; PM 25
Registration Division (TS-767C)

THRU: Paul F. Schuda, Chief *Paul F. Schuda*
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Attached, please find the Exposure Assessment Branch review of:

EPA Reg./File #:

Chemical Name: Tebuthiuron

Type Product: Herbicide

Company Name: Eli Lilly and Co.

Purpose: Submission of protocol for field dissipation study.

Date Received: 04/27/88 Action Code: 600

Date Completed: 5/02/88 EAB#(s): 80402

Monitoring study requested: Reserved

Monitoring study voluntarily:

Total Reviewing Time: 2h

Deferrals to: N/A

Ecological Effects Branch

Residue Chemistry Branch

Toxicology Branch

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information — Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME

1,6-bis(4-chlorophenyl)hexane

2. IDENTIFYING NUMBER

3. ACTION CODE

4. ACCESSION NUMBER

TO BE COMPLETED BY PM

1471-101

600

5. RECORD NUMBER

214292

6. REFERENCE NUMBER

1

7. DATE RECEIVED (EPA)

2-2-88

8. STATUTORY DUE DATE

9. PRODUCT MANAGER (PM)

Paul J. Edmunds

10. PM TEAM NUMBER

25

14. CHECK IF APPLICABLE

☐ Public Health/Quarantine

☐ Minor Use

☐ Substitute Chemical

☐ Part of IPM

☐ Seasonal Concern

☐ Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS

2-10-88

12. PRIORITY NUMBER

30

13. PROJECTED RETURN DATE

3-10-88

15. INSTRUCTIONS TO REVIEWER

- A. HED ☐ Total Assessment - 3(c)(5)
☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

- C. ☐ BFSD
D. ☐ TSS/RD
E. ☐ Other

B. SPRD (Send Copy of Form to SPRD PM)

- ☐ Chemical Undergoing Active RPAR Review
☐ Chemical Undergoing Active Registration Standards Review

F. INSTRUCTIONS

PLEASE review Protocol
to Fulfill (generic Data 1641
Soil Field Disposition

16. RELATED ACTIONS

17. 3(c)(1)(D)

- ☐ Use Any or All Available Information ☐ Use Only Attached Data
☐ Use Only the Attached Data for Formulation and Any or All
☐ Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

- ☐ TB ☐ EEB ☐ EF ☐ PL
☐ RCB ☒ EFB ☐ CH ☐ BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS								
	RESIDUE CHEMISTRY								
	ENVIRONMENTAL DATA								1
RD/TSS	CHEMISTRY								
	EFFICACY								
	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								

20. ☐ Label Submitted with Application Attached

21. ☐ Confidential Statement of Formula

22. ☐ Representative Labels Showing Accepted Uses Attached

23. Date Returned to RD (to be completed by HED)

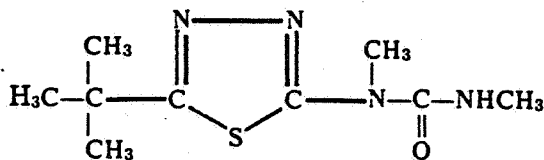
24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

1. Chemical:

Chemical name: N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N,N'-dimethylurea

Common name: tebuthiuron

Structure:



2. Test Material: 80% wettable powder.

3. Study/Action Type:

New field dissipation studies were identified as being needed for tebuthiuron by the Registration Standard which was issued July 30, 1987. The registrant has submitted a protocol for EPA approval.

4. Study ID:

LX199-03 (Tebuthiuron) Field Dissipation-Terrestrial Protocol
(FIFRA 164-1)

5. Reviewed By:

Michael R. Barrett, Chemist
Ground-Water Team
EAB/HED

Signature:

Date:

Michael R. Barrett
5/10/88

6. Approved By:

Patrick W. Holden, Team Leader
Ground-Water Team
EAB/HED

Signature:

Date:

Catharine E. Holden
5/10/88

7. Conclusions:

The protocol is adequate in so far as is described; however certain details are required (see recommendations).

The available environmental fate data (soil persistence greater than one year, Freundlich adsorption coefficients less than one in sandy soils) indicate leaching to ground water is a possibility. Residues have been found in some ground-water samples in Texas. Consequently, EAB has determined that a Small-Scale Retrospective Ground-Water Monitoring study is needed; a letter to the registrant requesting such a study is due to be sent by July 31, 1988. Such a study will complement the Field Dissipation studies already requested.

8. Recommendations:

In most respects, the proposed protocol is adequate. However, not enough information is given on the sites to be selected. The registrant should supply documentation that the study sites that are ultimately selected are typical in so far as possible of current usage, but with no previous use of tebuthiuron on the specific site, in so far as can be determined. At least one site should be located in a highly permeable soil such as a low-organic matter loamy sand without any underlying restrictive layers. The registrant must make every possible effort to document a two-foot residue-free vertical zone in all of the field dissipation studies. This might require sampling to greater than the proposed 120-cm depth. The field dissipation studies should be continued with soil samples taken for 60 months after treatment or until 90% of the applied pesticide has degraded, whichever comes first.

Analysis of selected samples should include metabolites other than metabolite "104" to determine if any of these metabolites might compose a significant portion of the terminal residue.

Yearly progress reports must be submitted to EPA with a short summary of all data that has been collected.

9. Background:

Field Dissipation Study was requested in 1987 Registration Standard.

10. Discussion:

The registrant proposes to conduct field dissipation studies in one site each in California, Nebraska, and Texas, with the sites to be areas "typical of the actual use area of tebuthiuron." No specific sites are proposed in the submitted protocol. Soil will be sampled to a 120 cm depth. No monitoring of ground water is contemplated in this proposal. Sampling will continue for 60 months or until "degradation rates have been established". The 60 month study period may be required since tebuthiuron is highly persistent.

11. Completion of One-Liner: N/A

12. CBI Appendix: N/A

Plant Science Projects Development and Registration Division
Lilly Research Laboratories
Elanco Products Company
Divisions of Eli Lilly and Company

P.O. Box 708
Greenfield, Indiana 46140
Telephone (317) 467-4000

ELANCO

February 1, 1988

Mr. Robert J. Taylor
Product Manager (25)
Office of Pesticide Programs (TS-767C)
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Taylor:

RE: TEBUTHIURON REGISTRATION STANDARD
PROPOSED PROTOCOL TO FULFILL GENERIC DATA REQUIREMENT
164-1: SOIL FIELD DISSIPATION

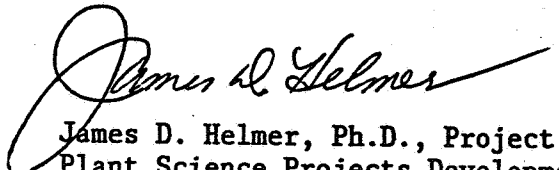
Enclosed for your review and consideration are three (3) copies of the proposed protocol for conducting the soil dissipation studies for fulfilling the generic data requirement for Study 164-1 in the Tebuthiuron Registration Standard. Since this research is very time consuming and costly, it is imperative that the Agency and Elanco Products Company are in complete agreement on study design and procedures before this research is initiated.

On Page 19 of the Tebuthiuron Registration Standard, it indicates that priority review will be given by the Agency on certain studies. Study 164-1 is so identified. Thus, it is requested an expeditious review be given the attached protocol in order for the research to be initiated on the date planned.

Thank you for your cooperation and assistance. Please call me at (317) 467-4877 if you have any questions.

Sincerely,

ELANCO PRODUCTS COMPANY
A Division of Eli Lilly & Company


James D. Helmer, Ph.D., Project Manager
Plant Science Projects Development
and Registration Division

JDH:cj

cc: Office of Compliance Monitoring

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Tebuthiuron

Page _____ is not included in this copy.

Pages 6 through 12 are not included.

The material not included contains the following type of information:

- _____ Identity of product inert ingredients.
- _____ Identity of product impurities.
- _____ Description of the product manufacturing process.
- _____ Description of quality control procedures.
- _____ Identity of the source of product ingredients.
- _____ Sales or other commercial/financial information.
- _____ A draft product label.
- _____ The product confidential statement of formula.
- _____ Information about a pending registration action.
- _____ FIFRA registration data.
- _____ The document is a duplicate of page(s) _____.
- _____ The document is not responsive to the request.

☒ Registrant protocol.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.